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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,611	09/08/2003	Per Elgard Pedersen	6523.200-US	9451

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NOVO NORDISK, INC.  
PATENT DEPARTMENT  
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PRINCETON, NJ 08540

EXAMINER
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CAMPBELL, VICTORIA P

ART UNIT	PAPER NUMBER
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4123

NOTIFICATION DATE	DELIVERY MODE
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01/10/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nnipatent@novonordisk.com  
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KSHL@novonordisk.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/657,611	<b>Applicant(s)</b> PEDERSEN ET AL.	
	<b>Examiner</b> VICTORIA P. CAMPBELL	<b>Art Unit</b> 4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6, 7, and 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/23/04, 3/22/04</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of the invention of Species A, which applicant has defined to read on claims 1-5 and 8 in the reply filed on November 19, 2003 is acknowledged.
2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This is the initial Office Action based on the 10/657,611 application filed September 8, 2003 and claims benefit of provisional applications 60/415,022 and 60/415,199, as well as EPO applications 02388059.4, 02388060.2, and 02388061.0. Claims 1-5 and 8 as elected are currently pending and considered below.

### ***Specification***

3. The abstract of the disclosure is objected to because the second paragraph listing "Fig. 1A" is not needed. Correction is required. See MPEP § 608.01(b).
4. The disclosure is objected to because of the following informalities:  
  
Page 2, line 14 reads "the pump offer the" but should read --the pump offers the--  
  
Page 8, lines 2-5 is awkward and should be rephrased.

Page 13, line 34 reads "as well as there" but should read --as well as their--.

Page 14, line 5 reads "112, 113 serving as inlet respective outlet" but should read --112, 113 serving as inlet and outlet respectively--.

Page 14, line 20 reads "area of the safety traces substantially" but should read --area of the safety traces is substantially--.

Page 14, lines 25-26, the phrase "a flow channel respectively a plurality of safety channels" is awkward and should be rephrased.

Page 21, lines 1-8 is awkward and should be rephrased.

Appropriate correction is required.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

6. Claim 8 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can not depend from any other multiple dependent claim (claim 4). See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by USPN 5,935,430 to Craig. Regarding the instant claims, Craig teaches the following:

1. A flow restrictor (Fig. 5, #312) comprising: a flow channel (Fig. 5, #334A and #334B) formed between at least a first member (Fig. 5, #314) and a second member (Fig. 5, #316) arranged in engagement with each other (Col. 11, lines 46-52), the flow channel having an inlet end portion in fluid communication with an inlet opening and an outlet end portion in fluid communication with an outlet opening (Fig. 5, apertures #338; Col. 10, lines 60-67), the flow channel comprising a generally U-formed portion with a pair of opposed first and second channel portions (Fig. 5, #334A and #334B; examiner interprets the end portion of a channel midway down Figure 5 on the right hand side to be connected to the portion of channel labeled by call-out #334B, thus making a U-shaped channel), and a safety channel arranged between the opposed first and second channel portions (Fig. 5, #321A and #321B), the safety channel comprising an end portion in fluid communication with an exterior space relative to the flow restrictor (no end portion of any of the embodiments in Figures 1-5 is shown; examiner interprets moats #321A and #321B to be open to the exterior, see also col. 10,

lines 38-43).

**2.** A flow restrictor as defined in claim 1, comprising a plurality of generally U-formed portions, each with a pair of opposed first and second channel portions (Fig. 5; more than one U-shaped channel is shown; additionally, Col. 10, lines 31-33 suggest that a serpentine path, which is widely accepted to be a series of U-shaped portions, could be used).

**3.** A flow restrictor as defined in claim 2, comprising a plurality of safety channels arranged between at least a portion of the opposed first and second channel portions (Fig. 5, #321A and #321B; Col. 11, lines 59-61 describe that the safety channel is adjacent to the first and second channel portions, therefore, examiner believes this would apply to singular and multiple channel portions).

**4.** A flow restrictor as defined in any of claims 1-3, wherein: the first member (Fig. 5, #314) comprises a first surface portion (Fig. 5, surface on which channels are etched) and the second member (Fig. 5, #316) comprises a second surface portion (Fig. 5, surface on which channels are etched), the first and second surface portions being arranged in opposed engagement with each other (Fig. 5, substrate #312 will be folded at #332 to place #314 in engagement with #316), and wherein traces are formed in at least one of the first and second surface portions (Fig. 5, #334A, #334B, #321A, and #321B), the traces in combination with an opposed surface portion forming the flow channel and the safety channel(s).

**5.** A flow restrictor as defined in claim 4, wherein the surface traces are formed in

one of the first and second surface portions (Fig. 4, surface #110A lacks the traces (shown as #121 and #114 in Fig. 3) to oppose traces #123 and #116 on surface #112; Col. 11, lines 40-45).

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USPGPub US 2004/0059316 A1 shows the applicant's flow restrictor without an additional safety channel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3726

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VPC

/Essama Omgba/  
Primary Examiner, Art Unit 3726